possible approaches to creating a disclosed catheter balloon structure. Nonetheless, in the present Office Action it is asserted that Jang "teaches conventional laser bonding". Use of the word "conventional" suggests that laser bonding is common or well known in the manufacture of balloon catheters.

This suggestion and the assertion about what Jang teaches are respectfully traversed. As Mr. Forman explains in the accompanying Declaration, there is no such thing as "conventional" laser bonding in the balloon catheter field. Schneider (USA) Inc. is the only known source of a balloon catheter made by laser bonding. Therefore, there is no ground for characterizing such balloon catheter or the method of making it as "conventional". Perhaps, by personal knowledge or based on an as yet undisclosed source, the Examiner is aware of grounds for characterizing a laser fusion bonded balloon catheter as "conventional." If so, it is incumbent upon the Examiner, pursuant to 37 CFR 1.107, to provide a complete explanation in the form of a signed affidavit.

There is further proof in the Forman Declaration as to the inadequacy of the Jang patent as to "teaching" laser bonding of a balloon catheter. The Forman Declaration confirms what has been asserted; namely, that Jang does nothing more than list laser welding as one of several alternative approaches to forming a bond. Other alternatives listed include vulcanization bonding, solvent bonding and ultrasonic bonding. As Mr. Forman explains in the Declaration, those of skill in the art do not employ any of these bonding approaches to balloon catheters. With reference to ultrasonic bonding, Mr. Forman points out that this type of bonding typically is used on flat plates, which is inconsistent with the physical constraints of annular or semi-circular bonds

that join balloon necks and catheter tubing.

Accordingly, there is no reason to surmise that, based on Jang, one skilled in the art is motivated toward selecting laser bonding for balloon catheters. This is particularly true where laser bonding is but one of several listed alternatives, some of which are known to those skilled in the art as not used and/or unsuitable.

In the present Office Action, it is asserted for the first time that fusion bonds on the neck regions would "inherently" be immediately adjacent the balloon tapered regions to prevent inflation of the neck regions upon balloon inflation.

This assertion is respectfully traversed. It appears to be based on an alleged "need" for a fusion bond to prevent the neck region from inflating along with the balloon. The error of this assumption is pointed out in the Forman Declaration, specifically at paragraph 12(b). The tendency of the neck region <u>not</u> to inflate along with the balloon has nothing to do with the location of the fusion bond. Rather, the neck region retains its shape because its wall thickness is on the order of four or five times the balloon wall thickness, and its diameter is substantially less than the balloon diameter. As seen from the equation in the Forman Declaration, both an increase in wall thickness and a decrease in diameter enhance hoop strength. Thus the neck region, primarily due to its greater thickness but also due to its smaller diameter, does not inflate along with the balloon.

Thus, there is no need for a fusion bond immediately adjacent the neck region in order to prevent neck region inflation.

The present Office Action includes the assertion that the

tapered regions of the Jang catheter would "inherently be substantially free of crystallization" to allow for proper balloon inflation and deflation.

This assertion is respectfully traversed, again with reference to the Forman Declaration, particularly paragraph 12(c). Mr. Forman explains that under conventional bonding methods the tapered regions are free of crystallization only if the bond is spaced apart from the tapered region axially by a sufficient distance, which is much greater than that claimed in accordance with the present invention. If the fusion bond is located within .030 inches of the tapered region and the balloon tapered region is to be substantially free of crystallization, then the balloon must be formed in accordance with the present invention, rather than by conventional fusion bonding methods.

As stated in the previous (December, 1992) amendment and repeated here: in the Jang patent, there is a total absence of any teaching that the tapered regions of a balloon are free of crystallization. Of course, freedom from crystallization is a desired result. The Examiner appears to assume that based in this desirability it further is inherent. This assumption is traversed. As pointed out in the Forman Declaration, the only way in which freedom from crystallization is achieved, in combination with the close location (within .030") of the fusion bond, is by using the bonding method as taught in the present application.

Should the Examiner have personal knowledge or evidence to the contrary, he is respectfully invited to produce such evidence in a signed affidavit pursuant to 37 CFR 1.107.

Claims 16-18, 22, 24-26, 28, 29 and 31 stand rejected under 35 USC 102(b) as anticipated, either by U.S. Patent No. 4,

950,239 (Gahara et al) or U.S. Patent No. 4,276,874 (Wolvek et al). The Wolvek and Gahara patents have been summarized in the December, 1992 amendment. Reasons given in that amendment as to why the present claims are allowable over these patents are incorporated in this Response.

In connection with both Gahara and Wolvek, it is asserted in the present Action that both patents would "inherently" have fusion bonds within less than .010 inches to .030 inches of the balloon tapered regions "to prevent inflation of the neck regions of the balloon." It also is asserted that these balloons "would further inherently have tapered regions substantially free of crystallization to allow for proper balloon inflation and deflation."

Again, both of these assertions are traversed. With reference to the assertion concerning preventing inflation of the neck region, reference is made to the Forman Declaration, paragraph 12(b). Reasons given above apply in this instance as well. Given the approach of providing neck regions of smaller diameters and thicker walls, as compared to the balloon itself, there is no foundation for the assumption that the neck region would automatically inflate with the balloon.

As to the assertion that the tapered regions are inherently substantially free of crystallization, reference is made to the Forman Declaration, particularly at paragraph 12(c). To the applicant's knowledge, when conventional balloon catheters formed by conventional methods have been free of crystallization, it is because the bonds, if fusion bonds, have been formed spaced apart axially of the tapered regions, by a distance substantially more than the .030 inch maximum spacing defined in Claims 16-31.

Claims 19-21 and 27 stand rejected under 35 USC 103 as

unpatentable over the Jang patent. In support of this rejection, it is stated that the "conventional design expedient" to minimize use of material and reduce cost would lead one of ordinary skill in the art to provide a shorter neck region and narrower band as claimed. However, one skilled in the art would not reduce cost in this manner if the result was a decrease in maneuverability due to crystallization in the balloon tapered region. Claims 19-21 and 27 incorporate all the features of the claims upon which they depend, including specifically the feature that the balloon tapered region is substantially free of crystallization. As pointed out in the Forman Declaration, conventional fusion bonding methods inherently lead to substantial crystallization in the balloon tapered regions if the fusion bonds are formed as close to the balloon tapered regions as claimed. If the Examiner has either evidence or personal knowledge to the effect that a fusion bond, formed by conventional methods, can be as close to the balloon tapered regions as claimed yet leave these regions substantially free of crystallization, he is, pursuant to 37 CFR 1.107, respectfully invited to present such evidence in the form of a signed affidavit.

Finally with respect to this rejection, the following statement is made, indeed repeated from the previous (September, 1992) Action:

> Note that Jang teaches using laser bonding, which as admitted by applicant is capable of the bond within the claimed dimensions.

The above statement is subject to an interpretation which is highly prejudicial to the applicant, and for this reason the undersigned attorney objects to its use and re-use. What the applicant "admits" -- indeed asserts -- is that when a balloon

catheter is formed by laser bonding, in the manner taught in the present application, the balloon can have the dimensions and spacing defined in Claims 19-21 and 27. The applicant, as pointed out above, denies that Jang "teaches using laser bonding." Again, Jang does nothing more than list "laser bonding" or "laser welding" among several choices, some of which are known to those skilled in the art to be inappropriate. Further, as pointed out in the December, 1992 amendment, and as pointed out by Mr. Forman in his Declaration (see especially paragraphs 10 and 11), even the use of laser bonding does not insure the spacing, dimensions and freedom from crystallization as claimed. Thus the original specification, the December, 1992 amendment and the Forman Declaration are consistent in refuting the assumption that laser bonding, per se, would inevitably lead to the claimed balloon catheter structure.

In the present Action, the Examiner has noted the applicant's failure to provide factual evidence to rebut the Examiner's argument of inherency or to show unexpected results. The Forman Declaration supplies such factual evidence which clearly refutes the inherency argument. Now, it is incumbent upon the Examiner, pursuant to 37 CFR 1.107, to provide facts to support his opinions.

Several assertions in the present Office Action shall now be addressed. Essentially, the Forman Declaration speaks for itself in refuting these assertions. The assertions are individually mentioned here, in the order presented in the Office Action.

1. The assertion that crystallization is eliminated if cooling is sufficiently rapid:

   The Forman Declaration speaks for itself in refuting this assertion.

2. The assertion that crystallization requires a polymer to be heated above the melting temperature and therefore be changed from a solid phase to a liquid phase:

The Forman Declaration speaks for itself in refuting this assertion (see paragraph 12(e)).

3. The assertion that even in conventional fusion bonding, only the neck region is raised to the melting point, since melting other regions (such as the balloon tapered region) would cause loss of structural integrity and shape:

Even if the neck region is assumed arguendo to be the only region raised to the melting point, such does not guarantee avoiding crystallization in the balloon tapered region. This is seen from paragraphs 12(e) and 12(f) of the Forman Declaration. Crystallization requires only heating above the glass transition temperature, not heating above the melting temperature. Further, the Examiner should note that if this assertion was true, conventional fusion bonding by heated jaws would be impossible, since it depends upon conduction of heat, radially inward toward the bonding site. This contemplates that the temperature of the neck region at its radially outward surface is greater than the temperature at the bond site. Under these conditions and under the proposed theory, the entire balloon neck should melt and lose its structural integrity and shape.

4. The assertion that applicant has failed to provide any factual evidence to support the opinion that a bond

obtained by applicant's laser bonding method is patentably distinguishable from a bond obtained from a conventional laser bonding method:

The Forman Declaration speaks for itself in refuting the above assertion, particularly in paragraphs 10, 11, 14 and 15. Also, please refer to the Forman Declaration at paragraph 12(a) and related material above in this Response as to the phrase "conventional laser bonding" in the context of balloon catheters.

To conclude, Claims 16-31 are drawn to a balloon catheter with a unique combination of a fusion bond in close proximity to the tapered region of a catheter balloon, and the absence of any substantial crystallization in the tapered region. This result is achieved only by careful selection of the laser energy source and the polymers forming the dilatation balloon and catheter, to match the laser energy wave length with a high energy absorption bandwidth of the polymer or polymers involved. Precise focusing of the laser energy at the bond site and operation of the laser in the tem_{00} mode, also contribute to a successful bond. Of the three references relied upon, only one of them so much as mentions laser bonding. This reference, the Jang patent, does nothing more than mention laser bonding, failing to teach or suggest any of the aforementioned features contributing to a successful fusion bond. Therefore, none of the cited references, nor any combination of them, can be said to anticipate the present invention.

Evidence is now of record to refute certain contentions advanced in this and the preceding Office Action. Since prior art rejections were grounded on these contentions, it is respectfully submitted that the evidence of record overcomes

these rejections, and demonstrates that Claims 16-31 define subject matter patentable over the cited prior art. Therefore, an early and favorable action allowing Claims 16-31 is requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Response Pursuant to 37 CFR 1.16 in response to the Office Action of March 31, 1993, in Application Serial No. 07/800,201, filed November 29, 1991 and the Declaration of Michael B. Forman are being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, postage prepaid, on June 28, 1993.

Frederick W. Niebuhr

Date: June 28, 1993